

REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

Claims 1-6 have been cancelled without prejudice.

Claims 7-22 stand rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

The Examiner contends that while the specification is enabling for preventing or treating *S. flexneri* with ST157 in cell culture, it does not reasonably provide enablement for treating any pathogen with any Abl tyrosine kinase inhibitor in humans. The Examiner also contends that the terms “a pathogen” and “an inhibitor of Abl tyrosine kinase” render the claims non-enabled.

As basis for the rejection, the Examiner again provides eight unsupported assertions. The Examiner then states that:

It is the Examiner's position that no credible evidence is presented to show that any such inhibitor will be effective to prevent or treat any infection, viral, bacterial or other pathogen in humans.

As pointed out previously, it is now well settled that a patent applicant enjoys the presumption that an invention can be practice as claimed; the burden is on the examiner to provide evidence to the contrary. Here, the Examiner has failed to provide any such evidence. The Examiner has merely provided his unsubstantiated opinion.

The studies provided in the instant application reveal a new role for Abl tyrosine kinase in pathogen infection. They demonstrate a requirement for Abl tyrosine kinase in the cellular uptake of a pathogen. While the invention is specifically exemplified using *Shigella* as the pathogen and the STI571 (Gleevec) (an FDA approved drug currently in use in treating chronic myeloid leukemia) as the Abl kinase inhibitor, Applicants teach in the application that the

invention is applicable to other pathogens using other Abl kinase inhibitors. The Examiner has offered no evidence as to why such would not be the case.

Until such time as the Examiner meets his burden, nothing further should be required of Applicants. Nonetheless, in an effort to advance this case, submitted herewith are articles (and Form PTO SB/08a listing same – which the Examiner is requested to initial and return) showing that inhibitors of the Abl kinases (Gleevec/ Imatinib), as well as dual Src/Abl kinase inhibitors such as Dasatinib and AZD0530, dramatically inhibit dengue virus infection and block assembly and maturation of the virus. The studies described in the articles employ the cell-based assays. While the authors of the enclosed PNAS paper indicate that they have developed an "efficient high-throughput" "immunofluorescence image-based assay suitable for identification of small molecule inhibitors of dengue virus", the same assay was used by Applicants to assay for compound inhibitors (Gleevec) or proteins (Abl kinases) that are involved in *Shigella* infection. The PNAS article relates one more in a growing list of pathogens that require Abl kinases for infection of mammalian cells, and that are amenable to treatment using Abl kinase inhibitors.

In view of the above, the Examiner is respectfully requested to reconsider his position. It is believed that, having done so, he will find withdrawal of the rejection to be in order.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

PENDERGAST et al
Appl. No. 10/734,582
June 13, 2007

Respectfully submitted,

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